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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,072	08/22/2003	Richard Kroczek	709181-999261	9651

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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,072	KROCZEK, RICHARD	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2006 and 19 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *77-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *77-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003 and 19 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/509,283.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment/remarks, filed 09/07/2006, are acknowledged.

Claims 1 – 76 have been cancelled.

Claims 77 – 82 have been added.

Claims 77 – 82 are pending.

2. Applicant's cancellation of claims 1 – 76 has rendered moot the restriction requirement, mailed 06/07/2006.

3. Applicant's comments regarding compliance with sequence listing requirements are acknowledged. The instant application, as amended, appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

4. Applicant's preliminary amendment, filed on 10/19/2005, and incorporating Figure 10 which was omitted from the original submission of the instant application, is acknowledged, and has been entered. Incorporation of the Figure does not appear to constitute the addition of new matter.

5. Applicant's amendment to the specification filed 09/07/2006 is acknowledged. However, the amendment has not been entered because the amendment does not refer to the specification as-filed by page number and line number, thus it is not clear what parts of the specification are to be amended. It appears that Applicant is trying to amend the Patent Publication, which is improper.

It is noted that Applicant is still required to amend the specification to disclose the accession number of the deposit of biological materials, date of deposit, and the complete name and address of the depository.

6. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. The Application USSN 09/509,283 upon which priority is claimed appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application.

7. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application USSN 09/509,283.

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title.

9. Applicant's IDS, filed 10/24/2005, is acknowledged, and has been considered.

Applicant states that the references have been provided in the priority application USSN 09/509,283. However, upon inspection of the parent application file, certain references could not be located, and have been lined through. Applicant is invited to resubmit these references to complete the record. The Examiner apologizes for the inconvenience to Applicant.

10. Applicant's submission on 09/07/2006 of a copy of the Declaration under C.F.R. § 1.132, regarding permanence and availability of deposited microorganisms, is acknowledged. The Declaration was originally submitted on 10/15/2002 in the parent application USSN 09/509,283.

11. Claim 77 is objected to because of the following informalities: the first use of the abbreviation "DSMZ" in the claims should be accompanies by the full name of the depository.

12. It is noted that claims 77 and 78 include recitations of 8F4 polypeptide, defined its properties. These recitations are essentially identical to those in the allowed parent Application USSN 09/509,283. Based in part on the record of USSN 09/509,283, and in particular the Judgment issued by the Board of Patent Appeals and Interferences (mailed 06/21/2005; Patent Interference No. 105,168), the polypeptide recited in the instant claims 77 and 78 appears to be free of prior art and of issues under 35 USC §112.

13. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 77 – 82 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a method of treating an asthmatic disorder, and a method of treating an organ transplant rejection, does not reasonably provide enablement for a method of treating a generically recited "immune disorder" or "autoimmune disorder." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

In evaluating the facts of the instant case, the following is noted: In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the efficacy of therapeutic antibodies can be species- and model-dependent, it is not clear that reliance on the experimental observations described in the instant specification provide the basis for employing the claimed antibodies for treating any immune or autoimmune disorders. For example, Blazar et al. (J. Immunol., 1996, 157:

3250 – 3259; see entire document, in particular, e.g. page 3257, column 2 first paragraph) disclose that issues such as tissue distribution, half-life, affinity and avidity obtained with various antibodies targeting costimulatory molecules might prove to be highly important in achieving a therapeutic effect. Therefore, any conclusion regarding the efficacy of 8F4 modulation on altering in vivo immune response should be interpreted in light of the specific reagent used (Blazar et al., see page 3257, column 2, paragraph 1). Thus there is no evidence that the animal model used in the experiments disclosed in the specification would be predictive of the therapeutic methods encompassed by the claims.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

Based on the evidence provided in related applications USSN 09/972, 524 and 09/823,307, it appears that the recited antibody is effective in treating an asthmatic disorder, or an organ transplant rejection, however, in view of insufficient guidance by the instant specification and the lack of predictability of the art to which the invention pertains with respect to 8F4 signaling pathway, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of the clinical protocols, and absent working examples providing evidence that the claimed methods are effective for treating any generically recited immune or autoimmune disorders.

15. The nonstatutory **double patenting rejection** is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 77 – 82 are rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 1 – 5 of **U.S. Patent No. 7,125,551**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the claims of the Patent.

17. Claims 77 – 82 are provisionally rejected on the ground of nonstatutory **obviousness-type double patenting** as being unpatentable over claims 21 – 35 of copending Application **USSN 09/823,307**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted that although the copending Application has been allowed and assigned a Patent Number, as of the date of this Office Action the Application has not issued as a Patent, and therefore, the present rejection is provisional.

18. The references made of record and not relied upon are considered pertinent to applicant's disclosure:

Tamatani et al. (US Pat. Pub. No. 2004/0151720; see entire document), and

Tamatani et al. (US Pat. Pub. No. 2004/0120945; see entire document).

The references teach and claim methods of treating autoimmune diseases by administering antibodies to a polypeptide (JTT-1/AILIM), which appears not to be patentably distinct from the instantly recited 8F4 polypeptide. Further, both the US priority and foreign priority dates of the cited references are earlier than those of the instant application.

However, it has been determined by the Board of Patent Appeals and Interferences that the claims of USSN 09/509,283, to which the instant application claims priority, and which are directed to the same antibody as recited in the instant claims, are not anticipated by the priority documents of Tamatani et al. (see the Judgment issued in USSN 09/509,283, mailed 06/21/2005; Patent Interference No. 105,168). Therefore, it is concluded that the above references are not anticipatory relative to the instant claims.

19. Conclusion: no claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
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October 26, 2006

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10/27/06